



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,593	04/15/2004	Raymond Pratt	109536.159WO1	6645
24395	7590	05/03/2005	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP THE WILLARD OFFICE BUILDING 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/824,593

Applicant(s)

PRATT ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-15-04</u> . | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1615

DETAILED ACTION

Receipt of IDS dated 4-15-04 is acknowledged.

Claims 1-20 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Rupreht et al (Anesthesiology, 1983).

Instant claim is directed to a method of treating substance abuse in a patient in need thereof comprising administering a therapeutically effective amount of a cholinesterase inhibitor. Rupreht et al studied nitric oxide withdrawal syndrome (substance abuse) in mice to examine factors the role in post-anesthetic excitation. Rupreht discloses that cholinesterase inhibitors, physostigmine and galanthamine or with opiate receptor blocking agent (naloxone) significantly reduced the predisposition to nitrous oxide withdrawal convulsions. Thus, Rupreht et al anticipates instant claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1615

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,895,841 to Sugimoto et al (Sugimoto) in view of Arendt et al (Acta Neurobiol Exp, abstract) or Ruppreht et al in view of Hurlbut (Emerg Med Clin North Am) and Sugimoto.

Instant claims are directed to a method of treating substance abuse in a patient in need of comprising administering a therapeutically effective amount of choline esterase inhibitor compounds possessing the claimed structure. Sugimoto teaches the compounds of the instant claims (col. 2-3, in particular the compounds of col. 3), as also admitted in the instant specification (page 14, lines 11-12). Sugimoto teaches that the compounds described have a strong and highly selective anti-cholinesterase activity, increasing the amount of

Art Unit: 1615

acetylcholine, exhibiting an excellent effect on a model with represent to disturbance of memory, and having a persistent activity and a high safety when compared with physostigmine which is a conventional drug in the art (col. 1). Sugimoto teaches the compounds as useful for treating diseases such as Alzheimer's, Pick's Disease, ataxias etc. While Sugimoto does not specifically teach the compounds for treating the claimed substance abuse, Sugimoto teaches that the compounds are useful in the treatment of diseases or conditions that are thought to be associated with deficiency of acetylcholine (col. 1).

Ruprecht et al, discussed above, studied nitric oxide withdrawal syndrome (substance abuse) in mice to examine factors the role in post-anesthetic excitation. Ruprecht teaches that cholinesterase inhibitors, physostigmine and galanthamine or with opiate receptor blocking agent (naloxone) significantly reduced the predisposition to nitrous oxide withdrawal convulsions.

Hurlbut teaches that major drug-induced psychoses are due to drugs such as cocaine, amphetamines, phencyclidine, cannabinoids, anti-cholinergic compounds etc. Hurlbut teaches that in addition to supportive measures, reassurances, and benzodiazepine, specific antidotes such as physostigmine for anti-cholinergic poisoning or urinary acidification to enhance excretion of amphetamines or phencyclidine in some patients. Neither Hurlbut nor Ruprecht teach the claimed compounds. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the acetylcholine esterase inhibitors of Sugimoto for treating drug induced withdrawal (Ruprecht et al) or toxicity induced by drugs such as cocaine, amphetamines etc.,

Art Unit: 1615

because Sugimoto teaches that the claimed compounds are more effective than the conventionally used physostigmine and other conventional anti-cholinesterase inhibitors. Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the compounds of Sugimoto for treating drug withdrawal symptoms or the toxicity, acidification and poisoning due to drugs such as cocaine, amphetamine, phencyclidine etc because Rupreht suggests treating drug withdrawal syndrome effectively with cholinesterase inhibitors and Hurlbut suggests treating the drug induced psychoses and the related poisoning and urine acidification with cholinesterase inhibitors. Thus, a skilled artisan would have exhibited to reduce the drug withdrawal symptoms as well as the associated poisoning with the cholinesterase inhibiting compounds of Sugimoto. Further, optimizing the amounts of compounds and administering by appropriate routes are within the scope of a skilled artisan because Sugimoto suggests various dosages and routes of administration.

Claim Rejections - 35 USC § 112

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim recites individual compounds (cocaine, amphetamine etc.) as well as groups of compounds identified by function (hallucinogen, psychedelic agent etc.) as substance abuse. However, the list constitutes an improper markush group.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615
April 27, 2005